

REMARKS

I. STATUS OF THE APPLICATION

Claims 1–28 were filed in the original application. In the Amendment and Response to Restriction Requirement mailed May 1, 2006, claims 1–12, 14, 21, and 26 – 28 were cancelled, claims 13, 16–19, and 22–23 were amended, and claims 29–45 were added. In the Response to Office Action mailed August 3, 2006 claim 29 was cancelled, and claims 13, 16, 18, 19, 22, 30, 31, 34, were amended. In the Amendment and Response to the Office Action mailed January 24, 2007 claims 13, 15–20, 22–25, and 30–45 were cancelled, and claims 46–90 were added. In the Request for Continued Examination and Amendment and Response to the Final Office Action of August 7, 2007, claims 63, 82 and 89 were amended, and claims 91-96 were added. In the present Amendment and Response to the Office Action of December 11, 2007, claims 46, 47, 50, 54, 56-58, 65, 66, 69, 73, 75-77, 80, 84 and 87 are amended, claims 91-96 are cancelled and claims 97 and 98 are newly added. Therefore, claims 46-90 and 97-98 are currently pending.

Applicants submit that the present amendments and additions to the claims add no new subject matter. With regard to “amplifying two or more segments of mitochondrial DNA” of currently amended claims 46, 65, and 84, “two or more amplification products” of currently amended claims 46 and 65, and “two or more primer pairs” of currently amended claim 84, support may be found throughout the Specification at, for example, Experimental Example 16, pages 39-41, and at Figures 19 and 20 of the Drawings. With regard to “identification of a missing person” of claims 97 and 98, support may be found throughout the Specification, at for example, page 2, lines 6-10. With regard to “detection and identification of a known bioagent” of claims 97 and 98, support may be found throughout the Specification at, for example, page 5, lines 8-10 and Figure 16 of the Drawings. With regard to “detection and identification of an unknown bioagent” of claims 97 and 98, support may be found throughout the Specification at, for example, page 8, lines 20-29, and Figure 17 of the Drawings. With regard to “elimination of an

individual as a crime suspect” and “identification of an individual as a crime suspect” of claims 97 and 98, support may be found throughout the Specification at, for example, page 3, lines 19-23, and page 4, lines 3-5. With regard to “identification of a location as a crime scene” of claims 97 and 98, support may be found throughout the Specification at, for example, page 1, lines 25- 27, and page 232, lines 24-26. With regard to “identification of a location as an accident scene” of claims 97 and 98, support may be found throughout the Specification at, for example, page 23, lines 12-14. With regard to “identification of evidence useful in a court of law” and “identification of evidence useful in a criminal investigation”, support may be found throughout the Specification at, for example, page 23, lines 14-16. With regard to “identification of one or more biological samples from a crime scene” of claims 97 and 98, support may be found throughout the Specification at, for example, page 23, lines 24-26.

Applicants note that all amendments of claims are made without acquiescing to any of the Examiner's arguments or rejections, and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG),¹ and without waiving the right to prosecute the amended or cancelled claims (or similar claims) in the future.

¹ 65 Fed. Reg. 54603 (Sept. 8, 2000).

II. RECORD OF THE INTERVIEW SUBSTANCE

Applicants provide herewith the following interview summary to be made of record with respect to the subject application. Applicants thank the Examiner for the helpful interview (hereinafter, "Interview"). The substance of the Interview was as follows:

Participants: Suryaprabha Chunduru, Ph.D. (Examiner), Jason Ferrone (Attorney), Lisa Mueller (Attorney), and Christopher Sappenfield (Attorney)

Date of Interview: May 21, 2008

Interview type: Personal

Exhibit shown or demonstration conducted: None

Claims discussed: Claims 46, 65, 84

Art discussed: Tatuch et al. (*Am. J. Hum. Genet.*, Vol 50, pp. 852-858, 1992), and Aaserud et al. (*Am Soc Spectrometry*, Vol. 7, pp. 1266-1269, 1996.)

Agreement with respect to the claims discussed: Examiner suggested that the arguments and proposed amendment will be considered.

Identification of principal proposed amendments of a substantive nature discussed: Discussed amending the claims to specify that two or more segments of mitochondrial DNA are amplified to obtain two or more amplification products.

General thrust of the Applicant's principal arguments: That the office action at issue fails to establish a *prima facie* case of obviousness with respect to claims 46, 65 and 84 in view of Tartuch and Aaserud.

General indication of any other pertinent matters discussed: Not applicable

General results or outcome of the Interview: Examiner agreed to consider Applicants' amendments and remarks.

III. CLAIM REJECTIONS

In the Office Action of December 11, 2008 there are 5 rejections to the claims.
The currently pending rejections are:

1. Claims 46, 51-52, 54-65, 70-71, and 73-83 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Parson et al. (*Int J Legal Med.*, Vol. 111, pp. 124-132, 1998) (hereinafter “Parson”) in view of Aaserud et al. (*Am Soc Spectrometry*, Vol. 7, pp. 1266-1269, 1996.) (hereinafter “Aaserud”).
2. Claims 53 and 72 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Parson in view of Aaserud as applied to claims 46, 51-52, 54-65, 70-71, 73-85, 89-90 and further in view of Oefner et al. (US 6,453,244) (hereinafter “Oefner”).
3. Claims 47-50 and 66-69 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Parson in view of Aaserud as applied to claims 46, 51-52, 54-65, 70-71, 73-85, 89-90 and further in view of Torroni et al. (*Genetics*, Vol 144, pp. 1835-1850, 1996) (hereinafter “Torroni”).
4. Claims 84-85, 87-90 and 95 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Tatuch et al. (*Am. J. Hum. Genet.*, Vol 50, pp. 852-858, 1992) (hereinafter “Tatuch”) in view of Aaserud et al.
5. Claim 86 is rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Tatuch in view of Aaserud as applied to claims 46, 51-52, 54-65, 70-71, 73-85, 89-90 and further in view of Baumer (*Am J Hum Genet.*, Vol 54, pp 618-630, 1994) (hereinafter “Baumer”).

A. Obviousness Rejection of Claims 46, 51-52, 54-65, 70-71, 73-83

In the Office Action of December 11, 2007 the Examiner has rejected claims 46, 51-52, 54-65, 70-71, 73-83 as allegedly obvious over Parson in view of Aaserud.

In the previous Amendment and Response to the Office Action of August 7, 2008 the Applicants note:

“The Examiner’s combination of Parson and Aaserud fails to teach or suggest the element “comparing said molecular masses of said one or more amplification products with at least one database comprising a plurality of known molecular masses from said one or more segments of mitochondrial DNA from a plurality of subjects, thereby reaching a forensic conclusion” (claim 46). Moreover, the Examiner’s combination of Parson and Aaserud fails to teach or suggest the element “comparing said base compositions of said one or more amplification products with at least one database comprising a plurality of known base compositions from said one or more segments of mitochondrial DNA from a plurality of subjects, thereby reaching a forensic conclusion” (claim 65).

Similarly, the Examiner’s combination of Parson plus Aaserud fails to teach or suggest the element “comparing base compositions of restriction fragments with at least one database comprising a plurality of known base compositions from one or more segments of mitochondrial DNA from a plurality of subjects, thereby reaching a forensic conclusion” (claim 69). Nor does the Examiner’s combination of Parson plus Aaserud teach or suggest the element “determining the relative amounts of said one or more amplification products from the abundance of mass spectral peaks corresponding to said one or more amplification products” (claims 61 and 80). (Amendment and Response to Office Action of August 7, 2008, pages 12-13)

In the Office Action of December 11, 2007 the Examiner agrees:

“Response to arguments:

With regard to the rejection of claims 46, 51-52, 54-65, 70-71, 73-85, 89-90

under 35 USC 103(a) as being obvious over Parson et al. in view of Aaserud et al., Applicants arguments are fully considered and found persuasive in part.

Applicants argue that the combination of Parson and Aaserud et al does not teach or suggest comparing base compositions from said one or more segments of mtDNA from plurality of subjects and fail to teach relative amounts of said amplification products.” (Office Action of December 11, 2007, page 6)

In turn, the Examiner does not identify the missing elements in references cited elsewhere in the Office Action of December 11, 2008. In view of missing elements of claims 46 and 65 in the Examiner’s combination of references, the Applicants respectfully request that this rejection under 35 USC 103(a) be withdrawn.

Accordingly, Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness. Nonetheless, in order to expedite the prosecution of the present application, without acquiescing to the Examiner’s rejection, and while reserving the right to prosecute the original or similar claims in the future, Applicants have amended claims 46 and 65 as discussed during the Interview to recite a forensic method of mitochondrial DNA analysis comprising the steps of providing a forensic evidence sample, amplifying “two or more segments of mitochondrial DNA” obtained from the forensic evidence sample to obtain “two or more amplification products”, determining the molecular masses of the “two or more amplification products” by mass spectrometry without sequencing the “two or more amplification products”, and comparing the molecular masses (claim 46) or base compositions (claim 65) of the “two or more amplification products” with at least one database comprising a plurality of known molecular masses (claim 46), or known base compositions (claim 65), from the “two or more segments of mitochondrial DNA” from a plurality of subjects, thereby reaching a forensic conclusion.

Applicants note that neither Parson nor Aaserud, alone or in combination, teach or suggest comparing the molecular masses and base compositions of two or more

amplification products from two or more segments of mitochondrial DNA to a database of known molecular masses and base compositions from a plurality of subjects to reach a forensic conclusion. As well, Applicants note that Parson and Aaserud fail to provide a teaching, suggestion or motivation to combine the cited references, or offer a reasonable expectation of success should the combinations be carried out.

In view of the above, Applicants respectfully request that this rejection be withdrawn.

B. Obviousness Rejection of Claims 53 and 72

In the Office Action of December 11, 2007 the Examiner has rejected claims 53 and 72 as allegedly obvious over Parson in view of Aaserud and further in view of Oefner.

Applicants note that dependent claims 53 and 72 are not obvious for at least the same reasons that base claims 46 and 65 are not obvious. As discussed above (Section III.A.), Applicants note that the Examiner's combination of Parson and Aaserud both individually, and in combination, fail to render claims 46 and 65 obvious. Oefner's description does not remedy the defects of the Examiner's combination of Parson and Aaserud. Thus, the Examiner's references fail to establish *prima facie* obviousness of the claims.

In view of the above, Applicants respectfully request that this rejection be withdrawn.

C. Obviousness Rejection of Claims 47-50 and 66-69

In the Office Action of December 11, 2007 the Examiner has rejected claims 47-50 and 66-69 as allegedly obvious over Parson in view of Aaserud and further in view of Torroni.

Applicants note that dependent claims 47-50 and 66-69 are not obvious for at least the same reasons that base claims 46 and 65 are not obvious. As discussed above

(Section III.A.), Applicants note that the Examiner's combination of Parson and Aaserud both individually, and in combination, fail to render claims 46 and 65 obvious. Torroni's description does not remedy the defects of the Examiner's combination of Parson and Aaserud. Thus, the Examiner's references fail to establish *prima facie* obviousness of the claims.

In view of the above, Applicants respectfully request that this rejection be withdrawn.

D. Obviousness Rejection of Claims 84-85, and 87-90

In the Office Action of December 11, 2007 the Examiner has rejected claims 84-85, 87-90 and 95 as allegedly obvious over Tatuch in view of Aaserud. Claim 95 is cancelled herein thereby rendering this rejection moot.

In the Office Action of December 11, 2007 the Examiner notes:

“It would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made to modify the method of mtDNA analysis as taught by Tatuch et al. in a manner as taught by Aaserud et al. by incorporating measuring base-composition by mass spectrometry for the purpose of enhancing sensitivity of the method for analyzing sequence variations in said target nucleic acid.”

(Office Action of December 11, 2007, page 4.)

Applicants respectfully disagree with the rejection, and submit that the Examiner has failed to establish a *prima facie* case of obviousness. Nonetheless, in order to expedite the prosecution of the present application, without acquiescing to the Examiner's rejection, and while reserving the right to prosecute the original or similar claims in the future, Applicants have amended claim 84 as discussed during the Interview to recite a method of characterizing heteroplasmy of “two or more segments of mitochondrial DNA” by amplifying “two or more segments of mitochondrial DNA” from a sample with “two or more primer pairs” to obtain a plurality of amplification products.

Applicants note that neither Tatuch, nor Aaserud, alone or in combination teach or suggest the limitation “amplifying two or more segments of mitochondrial DNA from said sample with two or more primer pairs” to obtain a plurality of amplification products. As well, Applicants note that Tatuch, Aaserud, and other references of record fail to provide a teaching, suggestion or motivation to combine the cited references, or offer a reasonable expectation of success should the combinations be carried out.

In view of the above, Applicants respectfully request that this rejection be withdrawn.

E. Obviousness Rejection of Claim 86

In the Office Action of December 11, 2007 the Examiner has rejected claim 86 as allegedly obvious over Tatuch in view of Aaserud, and further in view of Baumer.

Applicants note that dependent claim 86 is not obvious for at least the same reasons that base claim 84 is not obvious. As discussed above (Section III.D.), the Applicants note that the Examiner’s combination of Tatuch and Aaserud both individually, and in combination, fails to render claim 84 obvious. Baumer’s description does not remedy the defects of the Examiner’s combination of Parson and Aaserud. Thus, the Examiner’s references fail to establish prima facie obviousness of the claims.

In view of the above, Applicants respectfully request that this rejection be withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe that all claims of the present application are in condition for allowance. The issuance of a formal notice of allowance at an early date is respectfully requested.

Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicants encourage the Examiner to call the undersigned collect at (608) 218-6900.

Dated: June 10, 2008

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